



WESTERN STATES MEDICAL AND OTHER PROBLEMS WITH THE DOCTRINE CONCERNING FDA REGULATION OF COMMERCIAL SPEECH

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REGULATION OF COMMERCIAL SPEECH (2003 Third Year Paper)

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Western States Medical and Other Problems with the Doctrine Concerning FDA Regulation of Commercial
Speech

By Brian Kang

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Food and Drug Law
Peter Barton Hutt
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Introduction

The paternalistic behavior of the Food and Drug Administration ("FDA") has long been considered acceptable and even desirable government action. Disparities in information and power between consumers and manufacturers, and the potential for great harm in the misuse of food, drugs, or medical devices render FDA regulation welcome protection for American consumers. The felt need for protection is so strong that we require strict regulation of products even before they reach the consumer.¹ This sentiment, however, contrasts greatly with the laissez-faire American attitude towards regulations of speech. Free speech is one of the most cherished values in our society and closely guarded from government regulation. Commercial speech doctrine covers the area within which these two sentiments clash. Up until the *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*,² the outcome of this tension was simple: Regulation of commercial speech was always accepted because commercial speech was considered outside the protection of the First Amendment. *Virginia Bd. of Pharmacy*, however, changed all of this by protecting liquor ads despite their commercial nature and created an intermediate level of scrutiny under which to analyze regulations of this kind of speech.

Last year, the US Supreme Court for the first time struck down federal laws regulating the area of food and drugs.³ One of the reasons why the Court has never done so up until now is probably because the nexus between the safety and health of the American people and the FDA's authority to regulate food, drugs and medical devices is so close. Unlike other areas of regulations, FDA regulation of these items and their quality has a direct and potentially life-altering effect on the lives of individuals. Foods are unavoidable; drugs and medical devices are usually used when people are most vulnerable and in need of proper care. Many of these items do not have

¹See, e.g., Peter Barton Hutt and Richard A. Merrill, *Food and Drug Law* 475, et seq. (The Foundation Press, Inc. 1991) (pre-market approval demonstrated in the new drug application process).

²425 U.S. 748 (1976)

³Margaret Gilhooley, *Drug Regulation and the Constitution After *Western States**, 37 U. Rich. L. Rev. 901 (March 2003)

characteristics that allow the untrained eye to make assessments of their quality and all of these items deal with intimate areas of our persons: our bodies.

This paper will attempt to explain the current state of how commercial speech doctrine affects FDA regulation by looking closely to a recently decided case: *Thompson v. Western States Medical*.⁴ This case will then be used as platform from which to critique current commercial speech doctrine and suggest changes. This paper will then turn to other recent developments in the law, both in caselaw and legal scholarship, which may have profound effects on how we think about commercial speech.

Trends Leading Up to the Case

At least one of the reasons why there seems to be a change in recent years in the Court's attitude towards the legislative judgments about food and drug regulation is because the aforementioned concerns that drove the vestment of great powers in the FDA are giving way to two symbiotically reinforcing trends of the Court. One is the steady increase in protection of commercial speech. The other is the current Court's pronounced willingness to invalidate acts of Congress.

Strengthening of Commercial Speech

Commercial speech was not considered to pose any problems for the Court until the last quarter of a century.⁵ Congress or the states would regulate any such speech and the Court would not stand in its way because this kind of speech was not covered by the protections of the First Amendment.⁶ Regulation of speech, say in advertising,

⁴535 U.S. 357 (2002)

⁵*Virginia Bd. of Pharmacy*, 425 U.S. at 748, et seq.

⁶*Valentine v. Chrestensen*, 316 U.S. 52 (1942)

was allowed because it was well within the police powers of the state or the commerce powers of Congress.⁷ In 1942, the Court in *Chaplinsky v. New Hampshire* announced a two level theory regarding speech.⁸ The Court explained,

There are certain well-defined and narrowly limited classes of speech, the prevention and punishment of which have never been thought to raise any Constitutional problem. These include the lewd and obscene, the profane, the libelous, and the insulting or “fighting” words.⁹

The placement of commercial speech outside the protection of the 1st amendment was accepted because the reasons for protecting speech did not seem to apply.¹⁰ This changed in 1976 when the Court held in *Virginia Bd. of Pharmacy*, that speech does not lose its constitutional protection under the First Amendment just because it “proposes a financial transaction.”¹¹ The Court felt that commercial speech was beneficial because it informed people about their consumption choices and therefore had social value.¹² Consumers’ interest in having commercial speech available is twofold. The consumer benefits from the information that is embodied in the speech and the consumers also benefits from the competition that the speech allows. The majority found that even if the First Amendment is only relevant to public decision making in a democracy, commercial speech could still be relevant to such and end.¹³ However, the Court’s opinion did not clearly articulate why commercial speech should be treated like other forms of protected speech.¹⁴ In fact, subsequent cases demonstrated that the Court did not give commercial speech the full protection of the First Amendment because it felt that the speech was of a

⁷Id. at 54

⁸315 U.S. 568 (1942)

¹⁰*Valentine*, 316 U.S. 52.

¹¹*Virginia Bd.*, 425 U.S. at 762 (“our question is whether speech which does no more than propose a commercial transaction is so removed from any ‘exposition of ideas’ and from ‘truth, science, morality, and arts in general, in its diffusion of liberal sentiments on the administration of Government’ that it lacks all protection. Our answer is that it is not. [citations omitted]”).

¹²Id. at 765 (“It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed. To this end, the free flow of commercial information is indispensable.”)

¹³Id. (“even if the First Amendment were thought to be primarily an instrument to enlighten public decision-making in a democracy, we could not say that the free flow of information does not serve that goal.”)

¹⁴John H. Garvey and Frederick Schauer. *The First Amendment: A Reader* 376 (West Publishing Co. 1996).

different sort than the type usually thought of when considering the First Amendment.¹⁵ The information was usually more objective and verifiable than other types of speech. Therefore being less tolerant of inaccurate statements was acceptable because there is less of a fear about silencing the speaker. As a result, the form of the communication could be regulated without running afoul of any constitutional protections and the Government could even compel additional substantive information in order to inform consumers.¹⁶ Even the rule against prior restraints also did not apply to commercial speech.

One of the ways that the FDA responded to the Virginia Bd. of Pharmacies ruling is visible in their guidelines for food labeling issued in the Compliance Policy Guide (“Guide”).¹⁷ Books and other literature that was considered labeling for products (i.e. information presented to the customer in immediate connection with his or her view and purchase of the product) were often seized when the products they accompanied were confiscated for mislabeling. The FDA announced in its Policy that it would comply with the constitutional limitations by seizing only the products that were mislabeled and would then institute proceedings asking for an injunction to end the misuse of the offending literature.¹⁸

The next major development in the doctrine came in 1980 when *Central Hudson Gas & Electric Corp. v. Public Serv. Comm’n of N.Y.*,¹⁹ was decided. The United States Supreme Court announced a new test that would govern the constitutionality of regulations on commercial speech. The first part of the test asks whether the

¹⁵See e.g. *Board of Trustees of SUNY v. Fox*, 492 U.S. 469 (1989). See also *Posadas De Puerto Rico Associates v. Tourism Co. of Puerto Rico*, 478 U.S. 328 (1986); *Metromedia, Inc. v. San Diego*, 453 U.S. 490 (1981)

¹⁶*Bates v. State Bar of Arizona*, 433 U.S. 350, 383-84 (1977)

¹⁷Compliance Policy Guide No. 7153.12 (December 1, 1982)

¹⁸*Id.*

¹⁹447 U.S. 557 (1980)

regulation only constrains speech that is either misleading or proposes illegal activity.²⁰ If the answer is in the affirmative, then the speech is not protected by the First Amendment and the governmental regulation can not be invalidated on such grounds.²¹ If, however, the regulation puts restraints on speech that is neither misleading nor illegal, then the court must see if the regulation meets 3 other requirements. The regulation must serve a substantial governmental interest.²² This interest must be directly advanced by the regulation.²³ Lastly, the regulation should not be more extensive than necessary to serve that interest. ²⁴ If the regulation meets these requirements, then it is constitutionally permissible.

After this case, the doctrine created by Virginia Bd. of Pharmacies was further developed and explained by 44 Liquormart, Inc. v. Rhode Island.²⁵ There, the Court held that the greater power to outlaw certain forms of behavior does not include the lesser power to outlaw information distribution about that behavior if indeed it is not outlawed. The Court reasoned:

We fail to see how that syllogism requires the conclusion that the State's power to regulate commercial activity is 'greater' than its power to ban truthful, nonmisleading commercial speech. Contrary to the assumption made in *Posadas*, we think it quite clear that banning speech may sometimes prove far more intrusive than banning conduct. . . we reject the assumption that words are necessarily less vital to freedom than actions, or that logic somehow proves that the power to prohibit an activity is necessarily 'greater' than the power to suppress speech about it. ²⁶

As a result, the Government was not allowed to restrain speech about lawful activities, even if it has the ability

²⁰*Id.* at 564-565

²¹*Id.*

²²*Id.*

²³*Id.*

²⁴*Id.*

²⁵517 U.S. 484 (1996)

outlaw it, just because it disfavors the activity. The choice not to outlaw the activity insulates it with the First Amendment.

In the last quarter of a century or so, commercial speech has gone from no protection under the First Amendment to increasingly more and more protection. The Central Hudson test has indicated that an intermediate level of scrutiny should apply to restraints on commercial speech but the most recent caselaw indicates that many of the Justices on the Supreme Court are willing to extend protection even further.²⁷ Commercial speech soon may enter the company of political speech enjoying the same broad protections. A close reading of *Western States Medical* suggests a level of scrutiny higher than the intermediate level articulated in *Central Hudson* and intimates that commercial speech could get the full panoply of First Amendment protection but such a finding is not necessary in this case to strike down the regulation.²⁸ Justice O'Connor comments briefly on the uneasiness with which many Justices have with the *Central Hudson* test and Justice Thomas speaks explicitly to that effect.²⁹

Willingness Not to Defer

The Court's willingness not to defer the legislative judgments is another trend that explains last year's invalidation of a federal law pertaining to the regulation of foods and drugs.

The judgments of the Rehnquist Court constitute an "unprecedented wave of judicial activism."³⁰ Since 1995, the Court has struck down at least 33 acts of Congress.³¹ This means that the last 8 years contain one sixth of

²⁷See, e.g., *Liquormart*, 517 U.S. 501, 510-514 (opinion of Stevens, J., joined by Kennedy, and Ginsburg, JJ); *Liquormart*, 517 U.S. at 517. (Scalia, J., concurring in part and concurring in judgment; *Liquormart*, 517 U.S. at 518 (Thomas, J., concurring in part and concurring in judgment,); *Greater New Orleans Broadcasting Assn., Inc. v. United States*, 527 U.S. 173, 197 (1999) (Thomas, J. concurring in judgment).

²⁸*Western States Medical*, 535 U.S. at 367-368.

²⁹*Id.* at 377 (Thomas, J. concurring)

³⁰Ed Handelsman Shugerman. *Marbury and Judicial Deference: the Shadow of Whittington v. Polk and the Maryland Judiciary Battle*, 5 U. Pa. J. Const. L. 58, 61 (2002)

³¹*Id.*

the decisions invalidating federal statutes in the nation's history.³² This statistic can be partially attributed to the increased number of federal statutes passed due to the increasing role of the Government in the lives of ordinary citizens. However, the unexpected high frequency of invalidation of Congressional acts implies that there is at least a little less hesitancy among the members of the Court to put their own judgments above the legislatures. In *United States v. Morrison*, the Court unexpectedly cut into the Commerce Powers of Congress—powers that were, hitherto, considered almost limitless.³³ Chief Justice Rehnquist stated, “Ever since *Marbury*, this Court has remained the ultimate expositor of the constitutional text.”³⁴ Even though this may be true, the Court's use of its power of judicial review has been used much more sparingly throughout the history of the Court than it has recently.

This emboldened attitude of the current Court and the continuing growth of commercial speech protection have marginalized the concerns about health and safety that justified entrusting the FDA with broad powers when governing food and drugs and has yielded *Western States Medical*.

Thompson v. Western States Medical

Pharmacies brought suit against the Government alleging that 21 U.S.C.S. § 353a violated their constitutional rights to free speech. Section 353a creates an exception to the requirements for FDA approval of “new” drugs under the Federal Food Drug, and Cosmetic Act (“FDCA”).³⁵ Under that section, drugs compounded by pharmacists do not have to go through the rigorous application and approval process if the pharmacists do not solicit prescriptions for or advertise specific compounded drugs, but such activities concerning the compounding service as general matter is allowed.³⁶ Pharmacists argued that the limitations that the FDCA puts on this exception are

³²*Id.*

³³529 U.S. 598 (2000)

³⁴*Id.* at 616.

³⁵21 U.S.C.S. § 301 et seq.

³⁶21 U.S.C.S. § 353a: (c) Advertising and promotion. A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided

inconsistent with the First Amendment.³⁷

Background: The FDCA's Drug Approval Process

The FDCA sets up a plan for the regulation of manufacturing, and marketing of drugs that is motivated by the desire to protect the public from the harmful effects of drugs.³⁸ Section 505 of the FDCA states “no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [with the FDA] . . . is effective with respect to such a drug.”³⁹ “New drugs” go through a lengthy approval process that includes the submission of experimental data about clinical trials and other such tests that measure the safety of the drugs.⁴⁰ This process can take many years and is very expensive especially when considering the time and resources needed to conduct the experiments, going back and forth with the FDA about the proper amount and reliability of information, plus the need for the FDA to analyze the information. These new drugs must get approval from the Secretary of Health and Human Services by demonstrating that the drug is both safe and effective for each intended use.⁴¹ All new drugs must go through this process before introduction to commerce unless statutory provisions allow for an exemption. For example, many drugs were grandfathered into approval because of their common use before the enactment of the FDCA. It is not surprising that there are great financial incentives for drug manufacturers to avoid the new drug approval process. The concern with the possible danger of these chemicals has caused the FDA to implement standards for drug manufacturing and labeling so that consumers will be adequately informed about the proper use of the drugs and the accompanying dangers of the use.⁴² The manufacturers also have to register with the Secretary as a manufacturer and are subject to inspections.⁴³

by the licensed pharmacist or licensed physician.

³⁷Brief for the Respondents 1, 12 et seq.

³⁸Brief for the Petitioners 2-3

³⁹21 U.S.C.S. § 355 (a)

⁴⁰21 U.S.C.S. § 301 et seq.

⁴¹21 U.S.C.S. § 360

⁴²21 U.S.C.S. §§ 351, 352.

⁴³*Id.* at § 360(j) (each manufacturer must register with the Secretary a list of all the drugs it manufactures for commercial distribution); 360(h) (drug manufacturers are subject at a minimum to one governmental inspection every two years.).

“New drugs” are defined by the FDCA as “any drug... not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof...”⁴⁴ The Food and Drug Administration Modernization Act of 1997 (FDAMA) Section 503A exempts “compounded drugs” from the standard drug approval requirements of the FDA.⁴⁵

Drugs compounding describes a process of taking drugs approved for certain uses and altering them by adding to or changing the concentration of ingredients in order to create a drug with different characteristics—commonly having different physiological effects on the body.⁴⁶ This is done to customize drug use for people with special needs. For example, a person with an ailment but also has allergies to particular substances can receive a prescription for a compounded drug that serves to alleviate the ailment but also contains ingredients that suppress the allergic reaction. Since compounded drugs are individualized for particular patients, the cost of developing and seeking FDA approval for these drugs is not practical. However compounded drugs are invaluable to people who would not otherwise be able to take medication because of the personal idiosyncrasies of their bodies’ physiologies. The compounding of drugs is a customary practice of pharmacy and usually part of pharmacy school curriculum.⁴⁷ The FDCA largely left regulation of drug compounding to the states until the FDA suspected that some pharmacists were sidestepping the standard drug approval process by manufacturing and selling unapproved drugs as compounded drugs.⁴⁸ The FDA issued a Compliance Policy Guide in 1992 which warned that it “may . . . initiate federal enforcement actions. . . when the scope and nature of a pharmacy’s enforcement activities raises the kinds of concerns normally associated with a manufacturer and . . . results in significant violations of the new drug, adulteration, or misbranding provisions of the Act.”⁴⁹ The guide announced that the “FDA believes that

⁴⁴21 U.S.C. § 321 (p) (1).

⁴⁵21 U.S.C. § 353a

⁴⁶*Professionals & Patients for Customized Care v. Shalala*, 847 F. Supp. 1359, 1361 (S.D. Tex. 1994)

⁴⁷J. Thompson, *A Practical Guide to Contemporary Pharmacy Practice* 11.3 (1998)

⁴⁸*Western States Medical*, 535 U.S. at 362.

⁴⁹Compliance Policy Guide 7132.16.

an increasing number of establishments with retail pharmacy licenses are engages in manufacturing, distributing and promoting unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and that constitute violations of the [FDCA]."⁵⁰ In addition, the Guide set forth a policy that allowed compounding drugs either after the receipt of a prescription or before the receipt in limited quantities if the pharmacist could show a history for regularly filling prescriptions for a compounded drug and such activity did not amount to manufacturing.⁵¹

In 1997, Congress codified this policy in the FDAMA because it recognized the need for compound drugs and the concomitant safety concerns. Congress kept in mind, when it created the exception for compounded drugs for requirements of the FDCA, the factors which the Guide indicated raised the type of concerns that are associated with manufacturing.

The restrictions are as follows. The compounding must be done by a licensed pharmacist pursuant to a valid prescription or in limited quantities in anticipation of future to the receipt of such a prescription if there is a history of filling the prescription.⁵² Only approved ingredients shown to meet safety and manufacturing requirements can be used in compounding.⁵³ The ingredients may not appear on an FDA list of removed market items because they are unsafe or ineffective.⁵⁴ Compounding of a drug product that is the same as a commercially available drug can not be done with regularity or in "inordinate amounts."⁵⁵ The compounded drug may not be recognized by the FDA as one that raises concerns about safety and effectiveness.⁵⁶ Pharmacists can not deliver more than fiver percent of the compounded drug out of state if it has not entered into a "memorandum of understanding" with

⁵⁰Id.

⁵¹Id.

⁵²21 U.S.C.S. § 353a (a)

⁵³Id. at 353a (b) (1) (A)-(B)

⁵⁴Id. at 353a (b) (1) (C)

⁵⁵Id. at 353a (b) (1) (D)

⁵⁶Id. at 353a (b) (3) (A)

the FDA.⁵⁷ Lastly, the prescription for compounded drugs must be unsolicited.⁵⁸ Pharmacists can not “advertise or promote the compounding of any particular drug, class of drug or type of drug.”⁵⁹ However, advertising and promoting “the compounding service” is explicitly allowed.

The Case

A group of licensed pharmacists brought suit to enjoin the enforcement of the last requirement set forth in the FDAMA. They prepared promotional literature about compounding of specific drugs and wanted to distribute it to patients and doctors—an activity that they allege is protected by the First Amendment of the Constitution. The District Court held,⁶⁰ and the Court of Appeals for the Ninth Circuit later affirmed,⁶¹ that the provisions did not satisfy the test for constitutionally permissible regulation of commercial speech set forth in *Central Hudson*. The Supreme Court of the United States granted certiorari and in a 5-4 decision affirmed the judgment of the Court of Appeals.

O'Connor mentions, writing for the majority, that although the use the *Central Hudson* as the litmus for constitutionality in cases involving commercial speech is questioned by members of the Court, they felt that there was “no need to break new ground” to decide this case and so they proceeded to apply *Central Hudson*.⁶²

The first question posed by *Central Hudson* was not at issue in this case because the Government did not argue that the compounding of the drugs was an illegal activity. Neither did it argue that the advertisements of the

⁵⁷Id. at 353a (b) (3) (B)

⁵⁸Id. at 353a (a)

⁵⁹Id. at 353a (c)

⁶⁰*Western States Medical v. Shahala*, 69 F. Supp 2d 1288 (Nev. 1999)

⁶¹*Western States Medical v. Shahala*, 238 F. 3d 1090 (2001)

⁶²*Western States Medical*, 535 U.S. at 367-368

compounded drugs were misleading.⁶³

Consequently, the Court turned to see if the Government could satisfy the second prong of the Central Hudson test. The Government stated three interests that this regulation was aimed to serve. The Government wanted to protect the integrity of the new drug approval process because premarket approval is “necessary to ensure that those who promote and distribute new drugs, and realize profits from their distribution, undertake the investigations necessary to establish safety and effectiveness.”⁶⁴ The FDA’s experience with drug regulation has caused the FDA to require proof of the safety and effectiveness of a new drug “by rigorous, scientifically valid clinical studies rather than the impressions of individual doctors, who cannot by themselves compile and master the necessary information.”⁶⁵ Second, the Government also maintained the need to preserve the availability of compound drugs to treat the special needs of the public.⁶⁶ The last interest was the Government’s desire to strike the right balance between these two interests.⁶⁷ The Court did not dispute the substantiality of these three interests.

The third prong was not considered by the Court because the Court found that the fourth prong of the test, a showing that the need to make sure the regulation was not more extensive than necessary to serve the stated interests, was not satisfied.⁶⁸ The majority argued that there were other alternatives to achieve the same ends that were less restrictive on speech. Justice O’Connor, writing for the majority, stated “we have made clear that if the Government could achieve its interest in a manner that does not restrict speech, or that restricts less speech, the

⁶³Id. at 368.

⁶⁴Brief for the Petitioners 14

⁶⁵Id.

⁶⁶Id. at 14-15.

⁶⁷Id. at 16.

⁶⁸Western States Medical, 533 U.S. at 371.

Government must do so.”⁶⁹ Again she says, “If the First Amendment means anything, it means that regulating speech must be a last—not first—resort.”⁷⁰

The dissent, written by Justice Breyer, indicated that the public health and safety concerns of the Government should be given more weight and, alluding to *Lochner v. New York*,⁷¹ that this embodiment of the commercial speech doctrine may be used to strike many other health and safety regulation that ought to be a legislative or regulatory decision.⁷²

Concern with *Western States Medical*

Up until *Western States Medical*, the meaning of the last prong of *Central Hudson* was unclear.⁷³ At times the Court seems to have required that any regulation restricting commercial speech needed to be “narrowly tailored” to serve the substantial interests articulated.⁷⁴ At other times, the Court seemed to use a more lenient test allowing government regulations that were not the “least restrictive means” but were a “reasonable fit” for the problem or interest that the Government was trying to address.⁷⁵ *Western States* sets down a bright line rule that favors the former interpretation.⁷⁶ Under this rule, according to the Court, the restrictions on advertising fail because the Government could achieve its interests in a manner that restricts less speech.⁷⁷ However, this is a questionable conclusion because it is not at all clear that this regulation must be invalidated under this stricter standard. In addition, the choice of the more stringent standard should be reevaluated because, as this case

⁶⁹*Id.*

⁷⁰*Id.* at 373.

⁷¹198 U.S. 45 (1905)

⁷²*Western States Medical*, 535 U.S. at 389.

⁷³P. Cameron Devore, *Advertising and Commercial Speech: a First Amendment Guide* 6-30 – 6-31 (Practicing Law Institute, c1999-).

⁷⁴*In re Primus*, 436 U.S. 412, 438 (1978)

⁷⁵*Board of Trustees v. Fox*, 492 U.S. 469, 480 (1989)

⁷⁶*DeVore*, *supra* note 73 at 6-30 – 6-31.

⁷⁷*Western States Medical*, 535 U.S. at 371-372.

shows, the underlying values of the freedom of speech are not implicated to the same degree in the commercial context. The more lenient standard requiring a “reasonable fit” is more appropriate.

The restrictions on advertising are not more extensive than necessary to serve the governmental interest

The majority opinion says that the government interest is basically the need to “draw a line between small-scale compounding and large-scale drug manufacturing. That line must distinguish compounded drugs produced on such a small scale that they could not undergo safety and efficacy testing from drugs produced and sold on a large enough scale that they could undergo such testing and therefore must do so.”⁷⁸

However the way the majority has framed the substantial interests ignores the substance of the interests posited by the Government and revealed in its arguments. The majority includes in its opinion that the Government has explained,

compounding responds to a physician's prescription and an individual patient's particular medical situation, and that ‘advertising the particular products created in the provision of [such] service (as opposed to advertising the compounding service itself) is not necessary to . . . this type of responsive and customized service.’”⁷⁹

But by generalizing the governmental interests from balancing between maintaining the FDA drug approval process with the need to provide compound drugs to those who really need it on the one hand,⁸⁰ to balancing between large and small-scale manufacturing on the other hand,⁸¹ ignores much of what the Government has argued. The majority seems to think that, because the Government has claimed that advertising is “a fair proxy for actual or intended large-scale manufacturing,” that this is the only reason for why advertising is prohibited when in fact it is only one of the reasons for the regulation. The Government’s brief seems to make clear that, although large-scale

⁷⁸Western States Medical, 535 U.S. at 370.

⁸⁰Brief for the Petitioner 32-37

⁸¹Western States Medical, 535 U.S. at 370.

manufacturing of drugs is a concern, the regulation is aimed to make sure that the people who need the drug can get it and only those people. The regulation tries to draw a much finer line between the high uniform safety standards for drugs and the absolute necessity for individualized drugs for which FDA application and approval is impractical. This line is argued in Breyer's dissent.⁸² If this understanding of the governmental interests is adopted, the narrowness of the regulations and the inadequateness of alternate means will become apparent.

The majority proposed many non-speech-related means for achieving its formulation of substantial interest of drawing a line dividing large and small scale drug manufacturing.⁸³ The Court said that the other restrictions of the FDAMA may be adequate in achieving this interest. It also said that the Government could have adopted some of the other restrictions in the FDA's 1992 Compliance Policy Guide. The Court said,

For example, the Government could ban the use of 'commercial scale manufacturing or testing equipment for compounding drug products.' Compliance Policy Guide, App. To Pet. For Cert. 76a. It could prohibit pharmacists from compounding more drugs in anticipation of receiving prescriptions than in response to prescriptions already received. See *ibid.* It could prohibit pharmacists from 'offering compounded drugs at wholesale to other state licensed persons or commercial entities for resale.' *Id.*, at 77a. Alternately, it could limit the amount of compounded drugs either by volume or by number of prescriptions, that a given pharmacist or pharmacy sells out of State. See *ibid.*⁸⁴

and went on to propose alternatives not included in the Compliance Policy Guide such as "capping the amount of any particular compounded drug, either by drug volume, number of prescriptions, gross revenue, or profit that a pharmacist or pharmacy may make or sell in a given period of time."⁸⁵ The Court justified its judgment by saying that the Government was neither able to show why these alternatives will not work nor that they even

⁸²*Id.* at 379.

⁸³*Id.* at 372-373.

⁸⁵*Id.*

considered these alternatives.⁸⁶ It is interesting that the Court asks the Government to disprove the viability of each of the alternative methods hypothesized instead of first determining whether these less restrictive means for accomplishing the same end were in fact possible. The Court cites *Edenfield v. Fane* for the proposition that “it is well established that ‘the party seeking to uphold a restriction on commercial speech carries the burden of justifying it.’”⁸⁷ However, this doesn’t mean that Government needs do more than demonstrate that it has a substantial interest in the regulation and will answer why specific alternatives substantiated by the other party were not used. It would be too much to ask, and it is not what the majority here demanded, that the Government has the burden of showing why any possible alternative that passes through the mind of justice is not a viable option. So what does it mean to come up with the least restrictive means? It seems, especially with lawyers, that someone will always be able to come up with a less restrictive way of achieving an end. There will also be alternatives whose effectiveness cannot be either proved or disproved because they are not be amenable to assessment without considerable investments of time and resources, and exposure to risk. It seems that the most reasonable reading would be to require the Government to address any and all reasonable alternatives proposed by the other parties and justify why these reasons are not viable. A considerable amount of weight should also be given to the experience that the FDA has in regulating the drug industry.

Turning to the alternatives themselves, the Court can only say that these requirements are not more extensive than necessary under their, in my view, inaccurate formulation of the governmental interest at stake. If the government interest is to make sure that the compounded drug exception makes available such drugs only to the people that need it, then the inadequacy of the proposed alternatives and the narrow tailoring of the regulation becomes apparent. A ban on the commercial scale manufacturing or testing equipment for drug compounding does directly address the worry with large scale manufacturing but does not affect the ability for pharmacists to

⁸⁶*Id.* at 373.

⁸⁷*Western States Medical*, 533 U.S. at 373 (quoting *Edenfield v. Fane*, 507 U.S. 761, 770 (1993)).

sell small quantities of compounded drugs to people who do not need it but use them as a convenience. This thwarts the safety precautions embodied in the FDA new drug application process and its continuing requirements for manufacturers for the sake of satisfying a consumer's preference rather than need.⁸⁸ The balance struck by Congress was to allow exceptions from the drug approval process only where the need was great.⁸⁹ The other proposed alternatives that suggest limitations on the amount of compounded drugs produced or sold also misses the object of the statute. Such limitations do not ensure that compounded drugs go to the people who need it.⁹⁰ These limitations also can have a counterproductive effect if there is actually a need for the compounded drugs beyond the statutory limit. At that point, either people are unable to get the medicine they need or pharmacists expose themselves to liability for fulfilling the Congressional purpose for the exception given to compounded drugs.

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Once the governmental interest is properly understood, the regulation on advertising becomes an integral part of the FDAMA's purpose. Compounded drugs are only available by prescription. Congress has decided that the proper assessor of a patient's need comes from a physician. A prohibition on advertising the compounding of specific drugs works to ensure that the physician continues to be the one who makes this determination. The potential danger of different combinations and dosages of drugs requires that doctors make an assessment about a patient's need for such drug products independent of the persuasive influence of the patient. The effect of advertising on patients can only be to get them to ask their doctors for such products or at least ask about them. This poses a problem because the assumption underlying the whole system for prescription drugs is that the doctor will generate the prescription and not the patient. With advertising, patients will be able to affect the decisions of the doctors because of the doctor's desire to keep his or her patients happy rather than an independent

⁸⁸Western States Medical, 533 U.S. at 385.

⁸⁹Brief for the Petitioner 32-35.

⁹⁰Western States Medical, 533 U.S. at 385.

⁹¹*Id.*

assessment of the patient's health. The majority in this case criticizes the "questionable assumption" of the dissent that doctors will give to patients unnecessary medications.⁹² It dismisses evidence presented by the dissent that doctors will often satisfy requests for prescriptions for particular drugs that the patient has seen advertised, but does not point to any evidence to the contrary.⁹³

Describing the governmental interest as creating a balance between maintaining a safe and reliable drug approval process and providing drugs only to those patients who need them has been criticized by the majority as a "hypothesized justification" that was not argued by the Government as motivating the regulations.⁹⁴ According to the Court, imagining justifications is only appropriate when the Court is reviewing legislation for a rational basis.⁹⁵

Granted that the Central Hudson test is more demanding than the rational basis test and therefore requires the articulation of substantial interests by the Government, the majority overstates the absence of the "hypothesized justification" in the Government's articulation of its interests. To review, the majority identified three interests: 1) "preserving the effectiveness and integrity of the FDCA's new drug approval process and the protection of the public health that it provides." 2) preserving the availability of compounded drugs for those individual patients who, for particularized medical reasons, cannot use commercially available products that have been approved by the FDA." 3) "achieving the proper balance between those two independently compelling but competing interest is itself a substantial governmental interest."⁹⁶ Just considering these three statements, it is not a hypothetical stretch to say that the Government wants to make sure that the compounded drugs are available to those who need it and only those who need it. The first interest can't be read to mean that the new drug approval process

⁹²Western States Medical, 535 U.S. 374

⁹³1999 Prevention Magazine 10, at 32 (84% of consumers polled report that doctors accommodate their request for a specific drug); Henry J. Kaiser Family Foundation, Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising 3 (Nov. 2001) (more than 1 in 8 Americans have asked for and received a specific prescription from their doctor in response to advertising).

⁹⁴Western States Medical, 535 U.S. at 373-374.

⁹⁵Id.

⁹⁶Western States Medical, 535 U.S. at 368.

in and of itself is the goal, because the obvious concern that motivates it is public health and safety.⁹⁷ Setting up a regulatory scheme that will pursue the first interest to the utmost (i.e. protect everyone from untested drugs) while recognizing the second (individual necessity) seems to point to no other conclusion than the interest that Breyer states (i.e. providing these untested drugs only to those who need it and not to people who desire to use the drugs out of convenience).⁹⁸ This becomes even more likely with the emphasis on safety in the Government's brief.⁹⁹ The majority's formulation of what the Government's interest boils down to, i.e. the need to draw a line between large-scale and small-scale manufacturers, does not account for the prominence of the safety concern. This line the majority wants to draw may be one of the interests motivating the regulation but it is not the only one.

The majority makes the analogy between what the dissent doing in "manufacturing" a justification for the restrictions on advertising and a case where the Court tries to see if there is any rational basis possible to justify the legislation even though there is no evidence that this is really the case.¹⁰⁰ This analogy fails. As discussed above, the "hypothetical" interest is a natural if not logical outgrowth of the three interests expressly articulated by the Government.

The statute's basic exemption from testing requirements inherently creates risks simply by placing untested drugs in the hands of the consumer. Where an individual has a specific medical need for a specially tailored drug those risks are likely offset. But where an untested drug is a convenience, not a necessity, that offset is unlikely to be present.¹⁰¹

The need to protect the public health by keeping untested drug products from use where the benefits do not outweigh the risks is unlike the speculative justifications of rational basis review to which the majority compares

⁹⁷Brief for the Petitioner 19.

⁹⁸Western States Medical, 535 U.S. at 379.

⁹⁹Brief for the Petitioner 32.

¹⁰⁰Minnesota v. Clover Leaf Creamery Co., 449 U.S. 456 (1981)

it because it is the obvious intersection of the interests articulated.

Even if this governmental interest is asserted, the majority claims that “a fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway... would fail to justify the restrictions” because this would amount to a “fear that people would make bad decisions if given truthful information” and this can never be a justification for putting restraints on speech.¹⁰²

The response to this is twofold. The first is articulated by Justice Breyer. “It is an oversimplification to say that the Government ‘fears’ that doctors or patients ‘would make bad decisions if given truthful information.’ ”¹⁰³ The systematic effects of allowing many individual decisions about these compounded drugs would undermine the safety testing system such that society would lose the health and efficiency benefits that such a system was supposed to bring.¹⁰⁴ Once advertising is allowed for compounded drugs, manufacturers have an incentive to produce drugs and seek approval for the use which will be easiest to obtain. After a drug has been approved for such that it can be used in as an ingredient for compounded drugs, then the drug company can marketed the more risky uses of the drugs without having to through the expensive but beneficial drug approval process for this use. The increased availability of these drugs for non-approved uses means an increase in the probability that members of society will suffer harm from not understanding the risks or inadequate information about the product. This is harm that could have been avoided by the drug approval process.

¹⁰²Virginia Bd. of Pharmacies, 425 U.S. at 770.

¹⁰³Western States Medical, 535 U.S. at 387.

¹⁰⁴*Id.*

The second response is that the majority's arguments are completely out of place. The majority states that the "fear that people would make bad decisions if given truthful information about compounded drugs" is an unacceptable justification and goes against the very grain of the First Amendment.¹⁰⁵ Rather than limiting speech in a highly paternalistic fashion, "the First Amendment makes the choice for us" to allow information to freely flow so that we are better informed and less likely to make bad decisions.¹⁰⁶ However, it is truly curious that the majority demands information be made available for the public to inform them about decisions that are not theirs to make. People do not decide what medications to prescribe to themselves nor do we think that this should be the case. The majority's concern about making as much information as possible so that each actor can make informed decisions makes sense only in a situation where there is actually a decision to be made. This is why political speech, where everyone is a decision-maker, is the most closely guarded type of speech by the First Amendment and why in the area of medicine, and health care generally, the majority's reasoning is out of place. Society seems to feel comfortable with the fact that doctors are making the decisions when what is arguably most precious to us, our personal health, is at stake. Doctors make up what is most likely the most paternalistic profession there is. The medical profession is similar to the FDA in that it has been entrusted with the responsibility of protecting public safety where the stakes are high and the information hard to sift through. Part of the responsibility is to decide what information to communicate to patients so they can make informed choice when there is a choice to be made and also to make decisions that are best for the patients. Much of the reason why we entrust these responsibilities to doctors, and the FDA, is not necessarily because we think the public is ignorant, unthinking or credulous or fear that it will make irrational decisions, but because we have collectively decided or at least concede that such information is best understood through the lens of expertise. There is a market failure in the information available to the public. One part of the failure is that financial incentives will not drive information about the ineffectiveness and danger of drugs to the same extent that they

¹⁰⁵Id. at 374-375.

¹⁰⁶Id. at 375.

drive the attractive qualities of foods and products. Another part of the failure is not a failure in the traditional sense because rather than a lack of information, the amount of information is too great for the common person, a person whose profession does not require the constant and sole study of the human body, to consider and analyze when making decisions. We would rather outsource these decisions and considerations to people who are experts in this area. As a result society benefits because a large segment of society can put their time and efforts into other uses. So the paternalism that we normally associate with doctors is more about expertise than distrust. As a result, we don't expect doctors to explain to patients the details of how a chemical in the drug has an active site which will interact with a protein exposed in the cells lining the blood vessels which will inhibit the communication of the injured cells to macrophages and accompanying cells. The doctor can just say, "This will keep the swelling down." Unless we are no longer comfortable about the arrangement between doctors and the public at large, doctors will continue to make decisions for us including what drugs to prescribe. In this context, the values underlying the First Amendment are implicated the least. The argument can be made that advertising will allow patients to inform their doctors, the real decision-makers, of their special needs and remind the doctor of the availability of these drugs products. Yet there is no reason why these benefits can't be satisfied by the advertising of the compounding service, which is allowed by the FDAMA, rather than advertising the compounding of specific drugs.

The Fourth Prong of the Central Hudson Test Should Require a Reasonable Fit Rather than the Least Restrictive Alternative

In *Board of Trustees v. Fox*, the Supreme Court announced that the language of the Central Hudson "not more extensive than necessary" did not mean that the challenged regulation had to be the "least restrictive means."¹⁰⁷

From *City of Cincinnati v. Discovery Network, Inc.*¹⁰⁸ up until *Western States Medical*, the idea was developing

¹⁰⁷*Board of Trustees of SUNY v. Fox*, 492 U.S. at 479.

¹⁰⁸*City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993)

that the Government could not satisfy this prong if there were alternatives to the regulation that did not impinge on speech or did so at to a lesser extent.¹⁰⁹ During this time, it was unclear whether the existence of alternatives would be dispositive in striking down the regulation or whether the Court would take a more permissive approach and merely consider the existence of alternatives as factors when determining whether there was a reasonable fit between the governmental goal and the regulation.¹¹⁰ *Western States Medical* brought clarity by announcing a bright line rule: “We have made clear that if the Government could achieve its interest in a manner that does not restrict speech, or that restricts less speech, the Government must do so.”¹¹¹ This decision to adopt the stricter rule is not appropriate in the commercial context.

The First Amendment of the United States Constitution guarantees that, “Congress shall make no law . . . abridging the freedom of speech, or of the press.” This language is very broad and open-ended. All speech, however, is not protected and even within protected speech are different levels of protection.¹¹² Perjury and criminal solicitation are examples of unprotected speech. One of the considerations in determining to what extent speech is protected is by looking at the gravity of the evil produced by the speech.¹¹³ Constitutional law however adjusts the gravity of the harm by considering the probability that such an evil will occur. The clear and present danger rule expressed by Justice Holmes in *Shenck v. United States*,¹¹⁴ and the analysis in *Brandenburg v. Ohio*¹¹⁵ is an example of such a calibration. They “set a minimum probability below which the alleged danger feared from this kind of speech would never be sufficient to justify punishing the speech.”¹¹⁶ Not only does the probability of the harm need to pass a certain threshold, the gravity of the evil produced by the speech must be serious. In *Whitney v. California*, Justice Brandeis wrote, “Prohibition of free speech and assembly is a measure so stringent

¹⁰⁹Devore, *supra* note 73, at 6-30.

¹¹⁰*Id.* at 6-30 – 6-31.

¹¹¹*Id.*

¹¹²*Chaplinsky*, 315 U.S. at 571-572.

¹¹³See *Masses Publishing Co. v. Patten*, 244 F. 535 (S.D.N.Y.) *rev'd*, 246 F. 24 (2d Cir. 1917) (Learned Hand’s reliance on “incitement to illegal action” is an example of judges requiring a certain level of danger before outlawing speech.)

¹¹⁴249 U.S. 47, 52 (1919)

¹¹⁵395 U.S. 444, 447 (1969)

¹¹⁶William Van Alstyne, *A Graphic Review of the Free Speech Clause*, 70 *Calif. L. Rev.* 107 (1982).

that it would be inappropriate as a means for averting a relatively trivial harm to society.”¹¹⁷ The FDAMA’s regulation of advertising addresses a serious harm: a threat to the health and safety of the American public. In Justice Breyer’s words, “the risks associated with the untested combination of ingredients or the quicker absorption rate or the working conditions necessary to change an old drug into its new form can, for some patients, mean infection, serious side effects, or even death.”¹¹⁸ The probability of risk is also nontrivial. Once advertising becomes widespread, the likelihood of people exposing themselves to unapproved compounded drugs that they don’t need will increase. Drug manufacturers will have strong financial incentives to encourage this behavior and will be enabled to avoid the drug approval process which protects society at large. These considerations should inform the Court when determining the standard to hold the Government to. Requiring a strict test for the fourth prong of the Central Hudson test ignores the assessments of gravity and probability of harm that is important in First Amendment analysis. Just as there are differing levels of speech within First Amendment protection, there should be an understanding that within commercial speech, some speech is more dangerous than others. The consequences of food and drug regulation can be severe and irreparable. The FDA needs flexibility if it is to “pursue difficult (and often competing) objectives.”¹¹⁹

For most of this country’s history, the entire category of commercial speech was not protected. When it was given intermediate protection in *Virginia Bd. of Pharmacies*, even though the Court felt that commercial speech was valuable, the Court, at least implicitly, that the concerns underlying the protection of speech did not apply or at least did not apply as strongly. Justice Powell, on behalf of the Court, said,

¹¹⁷274 U.S. 357, 377 (1927)

¹¹⁸*Western States Medical*, 535 U.S. at 383.

¹¹⁹*Buckman Co. v Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 (2001)

[T]he 'commonsense' distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech. [cites omitted] The Constitution therefore accords a lesser protection to commercial speech than to other constitutionally guaranteed expression.¹²⁰

At the center of First Amendment protection are political issues and governmental policies. Then the protection gradually gets weaker starting with social and religious speech, down on to scientific, philosophic, economic, private, social scientific, aesthetic, and symbolic speech.¹²¹ Commercial speech brings up the rear and is on the edge of speech still protected. The varying degrees of protection are based on the philosophical foundations for why speech is important to us. An exploration of these philosophical foundations will be helpful in understanding why commercial speech lies at the border of free speech protection.

Theories Justifying the Freedom of Speech: Why Speech is Important to Us

One justification for the freedom of expression starts with what some consider the proper end of mankind: the realization of his or her character, abilities, and potential as a member of the human race.¹²² This process of self-realization is a deeply personal and individual process and involves the development of personality through formation of opinions and beliefs.¹²³ Every person must be allowed to express these opinions and beliefs. Therefore expression becomes "an integral part of the development of ideas, of mental exploration, and of the affirmation of self."¹²⁴ Free speech liberates people develop their faculties to the greatest extent.¹²⁵ The guarantee of the First Amendment protects this process of individual self realization and development.

¹²¹Van Alstyne, *supra* note 116, at 139-142.

¹²²Thomas I. Emerson, *Toward a General Theory of the First Amendment*, 72 *Yale L.J.* 877, 878-87 (1963)

¹²³*Id.*

¹²⁴*Id.*

¹²⁵Edwin Baker, *Scope of the First Amendment Freed of Speech*, 25 *UCLA L. Rev.* 964 (1978).

Related to the need for self-fulfillment through expression is the theory of autonomy. Autonomy includes the ability to share in the common decisions that affect oneself. Allowing humans to pursue autonomy means that each person respects their own ability to make decisions. You don't deny yourself or other people information because it is important for each person to hear, and judge for him or herself what is true and good. This means that the prohibition of ideas because they are too persuasive is an affront to human dignity because you deny people sovereign authority over their own reasoning ability. Therefore it is inconsistent with human dignity for the Government to protect me from false beliefs.¹²⁶

Another reason why we protect speech is because we value truth and believe that the best way to get at the truth is by providing a marketplace of ideas. A Holmesian, Darwinian, Posner-like idea is that you want the survival of the fittest ideas. Those ideas that work will survive. "Let [Truth] and Falsehood grapple; who ever know Truth put to the worse, in a free and open encounter?"¹²⁷ The more true or relevant an idea or doctrine is, the more likely it will withstand criticism and prevail. Truth corresponds with reality and will be effective. The best way to make sure that the truth is out in the arena of ideas is by protecting all types of ideas. The danger of allowing in false ideas to spread within the marketplace of ideas is lessened because they will be unable to withstand the criticisms of the market. In fact the best place for false ideas to be is in the realm of discussion so that they can be shown for the falsehoods that they are. John Stuart Mill wrote that silencing an opinion robs the human race, deprives us of correction, and deprives us of sharpening the truth. The best way to arrive at the truth and expose falsehood is if only Government does not hinder human reason with its own interests.¹²⁸

¹²⁶Thomas Scanlon, A Theory of Freedom of Expression, 1 Phil. & Pub.Aff. 204, 213-19, 222-224 (1972).

¹²⁷Milton. *Areopagitica*.

¹²⁸Popper, Karl. *The Open Society and Its Enemies*. (5th ed. 1966).

The search for the truth and for the best ideas is also part of what it means to participate in a democratic society. When society decided that all people were entitled to participate in the process of formulating common decisions, democracy became an end in itself and another reason for protecting the freedom of speech.

The process of democracy works best when all facts are considered for discussion. This means that all people must be permitted to participate because the greater the participation, the greater the variety of positions and opinions that can be considered and debated. The freedom of expression is necessary for people to participate as speakers, listeners, debaters, legislators.¹²⁹ In the political arena, the freedom of expression has particular significance for another reason. The party in control of the governmental machinery has the incentive and the ability to maintain the status quo and disempower its opposition.¹³⁰ The freedom of speech is necessary for a democratic society to function. "Once one accepts the premise of the Declaration of Independence- that governments derive 'their just power from the consent of the governed'—it follows that the governed must, in order to exercise their right of consent, have full freedom of expression both in forming individual judgments and in forming the common judgment."¹³¹

Theories Justifying the Freedom Speech Largely Inapplicable to Commercial Speech

Commercial speech is at the outer edges of the protection partially because much of commercial speech lacks the characteristics that make us value speech. For example, commercial speech usually consists of claims that are verifiable because the communication is about a product or service. Manufacturers' claims about products or

¹²⁹Emerson, *supra* note 122, at 880-887.

¹³⁰*Id.*

¹³¹*Id.*

services are usually easily tested because in the most common case, the consumer can compare the factual claims to his or her experience with the performance of what is sold and can make a judgment. Unlike abstract ideas or philosophical ideas, the communication is more likely to be objective and lack ideological content. Since we feel more confident about correctly assessing the truth or falsehood of a claim, there is less fear that the truth will be sacrificed when the marketplace of ideas is limited by a restriction on speech that addresses concerns about fairness or safety.

The purpose of commercial speech is also to promote a product or a service. Although it is true that speech like advertisement seek to persuade, it serves less of a truth-seeking function and more of a product or service promoting function. Even though persuasion is central to First Amendment values, not all types of persuasion are protected under the First Amendment. We have to go no farther than “threats” for an example.

Commercial speech is also not an expression that is central to the development of one's being or personality either. It is hard to see what transactions in commerce have to do with the desire and need to form opinions, beliefs, and an outlook on the world. The relationship is at best distant.

Likewise, a prohibition on advertising does not threaten the pursuit and maintenance of a democratic society. Commercial speech has very little to do with the political process.¹³² When the Government regulates commerce, there is also less of a fear that the Government is trying to suppress ideas than in the context of where the Government is regulating ideas directly. The participation of an individual in the political process also does not seem to be in danger. Whenever you regulate speech in the commercial context, you do not foreclose the issue of whether that speech should or should not be allowed. Unlike the political context, the commercial sphere is not self-regulating. In other words, commercial regulation has as its source the political sphere. As long the

¹³²Thomas H. Jackson and John Calvin Jeffries, Jr. Commercial Speech : Economic Due Process and the First Amendment, 65 Va. L. Rev. 1 (1979)

guarantee of freedom in the political sphere exists, limitations on speech in the commercial context can always be reconsidered, debated and overturned in the future. However the political sphere regulates itself. So the danger in limiting speech here is much greater because there is no readily available outside source that can institute change if a limitation on speech disables itself from correction.

The justification for speech that is most applicable to commercial speech is the concern about autonomy. This is what the majority latches onto saying, “it is a matter of public interest that economic decisions, in the aggregate, be intelligent and well-informed. To this end, the free flow of commercial information is indispensable.”¹³³ The majority emphasized the need for individuals to be allowed to determine for themselves the worth of information provided by commercial actors.

“The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented.”¹³⁴

However this is true only to the extent we feel the autonomous actor is in a relatively well-informed position. The commercial context varies greatly in how much the recipient of commercial speech has access to all the relevant information. Commercial speakers are usually in much better information than their hearers. They are able to take advantage of this disparity and have the financial incentives to do so. Fraud and false statements in securities filings are two examples where autonomy theory seems to prove too much. The theory forces us to accept “social costs that are too high—or put the other way around, it forbids government intervention when (all things considered) we would prefer to have it.”¹³⁵ So autonomy is valuable but is not absolute and must be weighed with competing interests.

¹³³Western States Medical, 535 U.S. at 366 (quoting Virginia Bd. of Pharmacies, 425 U.S. at 765).

¹³⁵Garvey, *supra* note 14, at 132.

Since most of the reasons why we protect speech are inapplicable to the commercial context and the ones that are applicable must be limited with other legitimate concerns, the scrutiny with which the courts review limitations on commercial speech should not be as strict as it was in this case. This is not an argument that commercial speech should lose all of its protection, because it, like all information, has social value. The point is restrictions on commercial speech do not raise the same concerns to the same degree that restrictions on other forms of speech do. The Government should be given more flexibility depending on the interest it is pursuing and the degree to which we think autonomy, self-expression, democracy, and truth are threatened.

With respect to the restrictions that the FDAMA put on advertising, the threat to self-expression, democracy and truth were essentially absent. The concern for autonomy was misplaced also because, as discussed above, the patients for whom the pharmacists wanted to advertise are not in a position to make the decision about which prescription drugs to use. The interest the Government was pursuing also has a higher degree of importance than other regulations. Drug use is inherently dangerous because once a drug is put in the body the effects are often irreversible. The lack of testing of new drug compounds can result in injury and death because drug interactions can often produce effects that even physicians cannot predict. Using untested compounded drug is also costly because it will cause patients to forego other available and more effective treatments by putting their faith in a drug product of unreliable effectiveness.

The inflexible rule resulting from the Western States Medical interpretation of the fourth prong of the Central Hudson test is inappropriate because it doesn't account for the variability in the commercial context. The Court's invalidation of the FDAMA restrictions on advertising is a good example of how this rigid rule thwarts important

governmental aims even though the regulations do not raise the First Amendment concerns that justify the rule.

Recent Developments Relevant to the Doctrine of Commercial Speech

*Kasky v. Nike, Inc.*¹³⁶

The Supreme Court of United States recently granted certiorari to the California Supreme Court ruling dealing with commercial speech. This case will be of great interest to the FDA and to Congress because the issue is the very definition of commercial speech. Nike has been thrust into the public eye recently because many human rights and consumer groups have criticized it for its manufacturing and labor practices in foreign countries. Kasky brought suit under California's Unfair Competition Law and false advertising law. These two laws only give rise to a cause of action if the speech is commercial speech. Kasky alleges Nike made false statements in response to the attacks on Nike's labor practices. Nike distributed statements for public relations purposes in the form of letters to newspapers, to university presidents, athletic directors and issued press releases. Nike claims that this activity amounts to noncommercial speech and therefore the causes of action are not sustainable.

The California Supreme Court held that causes of action were sustainable because the statements made by Nike amounted to commercial speech. The Court set up a three part test for determining whether speech is commercial or noncommercial.¹³⁷ First, the court must determine if the speaker is "someone engaged in commerce."¹³⁸ If so, the court must determine whether the intended audience is "likely to be actual or potential buyers or customers of the speaker's goods or services or persons acting for actual or potential buyers or customers, or person (such as reporters or reviewers) likely to repeat the message to or otherwise influence actual or potential buyers or

¹³⁶27 Cal. 4th 939, 45 P.3d 243 (Cal. 2002), cert. granted, 2003 WL 77085, 71 USLW 3319 (U.S. Jan. 10, 2003).

¹³⁷*Kasky*, 27 Cal. 4th at 960.

¹³⁸*Id.*

customers.”¹³⁹ Lastly, the court must conclude that the “speech consists of representations of fact about the business operations, products, or services of the speaker . . . made for the purpose of promoting sales of, or other commercial transactions in, the speaker’s products or services.”¹⁴⁰

This review of this test by the Supreme Court is significant because the three prongs of this test are “described so broadly that a huge range of corporate communications could become the subject of UCL claims.”¹⁴¹

The dissent felt that test was overly broad and were not supported by the principles of the First Amendment.¹⁴² Commercial speech, according to the dissent, should only be defined by its content. If the decision of the Court is allowed to stand, speakers engaged in commerce will not be allowed to “participate in public debates over public issues.”¹⁴³ Public debate will also be skewed because Nike will not enjoy the same protection when it speaks that its critics will.^{144 145}

The outcome of this case will potentially have a strong impact on what the FDA will be allowed to regulate and what powers Congress can vest in the FDA. For example, misstatements made by drug or food manufacturers to the FDA during registration, or during inspections could be protected the First Amendment. The FDA’s power

¹³⁹Id.

¹⁴⁰Id. at 961.

¹⁴¹Devore, *supra* note 122, at 2-23.

¹⁴²Kasky, 27 Cal. 4th at 981.

¹⁴³Id. at 982.

¹⁴⁴Id. at 985 (“only speakers engaged in commerce are strictly liable for their false or misleading representations...meanwhile, other speakers who make the same representations may fact no such liability, regardless of the context of their statements”).

¹⁴⁵Id. at 970 (“when Nike tries to defend itself from these attacks, the majority denies it the same First Amendment protection Nike’s critics enjoy”).

to regulate the activities of food, drug, cosmetics and medical devices may substantially increase or decrease depending on how the Court rules.

The Supreme Court may also take this opportunity to strengthen commercial speech which could mean that Central Hudson test is no longer applicable. In *Lorillard Tobacco Co. v. Reilly*,¹⁴⁶ Justices Kennedy, Scalia and Thomas expressed dissatisfaction with the test because it was not protective enough of truthful, non-misleading information.¹⁴⁷ The fact that this decision produced nine opinions reflects the difficulty in or at least different conceptions of the application of the Central Hudson test.¹⁴⁸ If indeed, the Court uses this opportunity to strengthen commercial speech protection or broaden its scope, the FDA will have even more difficulty in fashioning regulations that don't run afoul of the First Amendment.

Although Court seems to be heading towards strengthening commercial speech protection and will reverse the judgment of the California Supreme Court, the Court should not because Nike's speech amounted to representations of fact are commercial in nature. It may be appropriate, however, to invalidate or modify the test announced by the California Supreme Court.

When determining whether speech is commercial or not, the content, as the dissent points out, should be the main focus on the analysis.¹⁴⁹ It is entirely possible for pure economic actors, to speak politically and such speech

¹⁴⁶533 U.S. 525 (2001)

¹⁴⁷*Id.* at 570 (Kennedy, J., concurring); *Lorillard*, 533 U.S. at 570 (Thomas, J., concurring).

¹⁴⁸Rosalie Berger Levinson, *Constitutional Law: State and Federal Constitutional Law Developments*, 35 *Ind. L. Rev.* 1263 (2002)

¹⁴⁹*Kasky*, 27 Cal. 4th at 981-982.

should receive the full protection of the freedom of speech even if it is economically motivated. However it is not clear that the California test would categorize this speech as commercial. The weight given to each of the prongs is only clear in the minds of the individual Justices.

The dissent criticizes the majority for making the determination of the speaker practically dispositive of the speech's commercial character.¹⁵⁰ Yet this is not clear. For example, if Nike had only made statements about what the child labor laws should look like or whether outsourcing labor to other countries is beneficial for everyone involved, it would be making purely policy arguments that should be protected by the First Amendment. The California Supreme Court's ruling in *Kasky* does not indicate that this hypothetical speech would be considered commercial just because Nike is "someone engaged in commerce" and clearly would have a financial interest in the resolution of these policy issues.

An assessment of the speaker and the audience should only be made only in so far as they are indicators of the speech's content. Although giving to corporations, fictitious entities with the main goal of profit maximization, the same freedom of speech guarantees that human beings enjoy seems strange because once again many of the justifications for free speech do not exist, these entities can also contribute to public debate. The burden of the courts is to separate when these entities are contributing to public debate and when they are selling their products or services. The dissent argues that the two are "inextricably intertwined" and so non-commercial speech protection should be given to the entire ball of yarn in order to protect its non-commercial elements.¹⁵¹

This seems wrong. Although these elements are often found together, especially in a situation such as the one Nike is in, it is reasonable, although not easy, to believe that courts can differentiate when a commercial actor is making a claim about or promoting its product or business, and when the actor is speaking more broadly. By

¹⁵⁰*Id.*

¹⁵¹*Id.* at 988.

separating the commercial and noncommercial elements, the Court can preserve open and robust public debate while at the same time regulating false and misleading statements of fact. Nike's statements should be regarded as commercial speech only in so far as they make representations about the source of their products and their business practices.

There is also a question about what is lost when Nike is unable to compete with its critics on the same terms. All that is lost is the availability for Nike to make misleading and false statements about its business practices. Will the public debate be so handicapped on the account that when Nike speaks about itself it must be honest? Maybe. We may want to preserve a level playing field for public debate purely out of the principle of equality. However, this would not be the first time parties are treated differently in the context of free speech. *New York Times Co. v. Sullivan*¹⁵² requires public figures to demonstrate malicious intent, an almost impossible standard to satisfy, to win a libel action, even though they can be sued for the same cause of action for much less. In a case where the public interest is strong enough, as it was in *Sullivan*, certain parties will have to take the brunt of the social costs. The corporate speech context may be such a case.

The Effect of Irrationality on Commercial Speech

Recently a number of articles have been published within the legal community critiquing the concept of the reasonable or rational person.¹⁵³ Many of the articles describe how the fundamental assumption of law and economic analysis, and an assumption of the law generally, that people act rationally, is being disproved by behavioral research. We all have biases that defy rationality and many of them are even resistant to education.¹⁵⁴

¹⁵²376 U.S. 254 (1964).

¹⁵³See, e.g. Jon D. Hanson and Douglas A. Kysar. Taking Behavioralism Seriously: The Problem of Market Manipulation 74 N.Y.U. L. Rev. 630 (1999) (discussing how manufacturers manipulate consumer perception)

¹⁵⁴Hanson, *supra* note 153, at 647-668

It has been proposed that the “reason commentators often deny claims that advertising is harmful is that such claims represent an assault on many people’s cherished self-image as rational actors.”¹⁵⁵ We would probably all agree that advertising works, but we are far less inclined to think that it works on ourselves.¹⁵⁶

Beyond shaking the foundations of tort law, these findings if verified will require a reassessment of First Amendment doctrine. Much of free speech protection is based on the value of information to the audience and the ability to process the information rationally. If people are shown to be unable to process the information rationally in certain situations, then in those situations, the worth of the information and the justifications for free speech must weaken. Giving additional information has even been found to be detrimental to the decisions making process.¹⁵⁷ It is possible that legal academia and courts will ignore the irrationality of human beings for First Amendment purposes because it either does not want to recognize irrational behavior as legitimate or it may be too difficult to create a new doctrine that accounts for individual irrationality, but it would seem unwise to ignore these findings and make no adjustments to the law whatsoever.

If free speech doctrine were to change however, fashioning the doctrine may not be as difficult as we would expect. It may seem an intractable task to formulate doctrine to account for everyone’s irrational idiosyncrasies, but the studies seem to indicate that people act irrationally in predictable ways.¹⁵⁸ If this is the case, then adjustments should be made to how we think about free speech and commercial speech in particular to accommodate for our lapses in rational thinking. The reason why obscene speech and threatening speech (even though it constitutes

¹⁵⁵Tamara R. Piety, *Crave New World: An Exploration of the Psychology of Advertising Addiction and its Implications for Commercial Speech* (May 2000)

¹⁵⁶Piety, *supra* note 155, at 40.

¹⁵⁷Hanson, *supra* note 153, at 665.

¹⁵⁸Piety, *supra* note 155, at 31-32; Hanson, *supra* note 153, at 647-668 (explaining the phenomenon of confirmatory bias, motivated reasoning, optimism bias, cognitive dissonance, illusion of control, hindsight bias, availability and representativeness bias, anchoring and adjustment effect).

a form of persuasion) are not protected by the freedom of speech is because they bypass our rational faculties and trigger a visceral reaction. This reasoning will apply more broadly if we find that other types of speech, like commercial speech, will also cause us to forego our reasoning abilities.

It is possible what legal scholars are debating about has been understood by corporations and advertising companies for years. Commercial advertisers are in the business of creating desire.¹⁵⁹ Marketing strategies probably have the best literature on how people behave towards certain stimuli. These actors have the most to gain from the exploitation of people irrationality.

In creating the desirable perceptions, commercial advertising relies heavily on non-rational thought processes. Commercial advertising is not primarily concerned with providing...information as it is with creating a feeling associated with a brand."¹⁶⁰

Advertisers are, according to one author, manipulating our anxieties and self-esteem in order to sell products.¹⁶¹ They may be thought of satisfying a need or problem, but at least in some cases they are also responsible for creating it.¹⁶²

Commercial speech doctrine may have to take a sharp turn from its current trend of increasing protection. Much of the doctrine is based on the listener's right to hear the information available and use their own powers of deduction to make choices. According to the studies, "based on what we know about the fallibility of human rationality along certain lines, the notion that either advertising is inconsequential or that people are rational ... appears unfounded."¹⁶³ If advertising does not implicate the reasoning faculties the basic reason for protecting speech

¹⁵⁹Piety, *supra* note 155, at 11-12.

¹⁶¹Piety, *supra* note 155, at 70.

¹⁶²Jean Kilbourne, *Deadly Persuasion* 135 (1999) (introduction of television to Fiji correlated with an increase of teenage girls' weight control via vomiting from 3% to 15% and a 100% increase in the incidence of dieting for these girls.)

¹⁶³Piety, *supra* note 155, at 7.

is gone. Of course, advertising could never, I hope, completely forgo people mental capacities and so there will always be a need to protect information. The extent of the protection however is up for grabs.

“Paternalism” seems to be one of the most distasteful words in the legal community. However, the connotations of paternalism may have to change if we find that the “offensive assumption that the public will respond ‘irrationally’ to the truth” turns out to be true.¹⁶⁴

¹⁶⁴44 Liquormart, 517 U.S. at 503.